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10/650,326	08/28/2003	Keith A. Hruska	STK-P01-599	6882

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EXAMINER

BORGEEST, CHRISTINA M

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1649

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/650,326	Applicant(s) HRUSKA ET AL.	
	Examiner Christina Borgeest	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56,69-71 and 78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56,69-71 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/25/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 November 2009 has been entered.

Claim 56 and 78 are amended; claims 1-55, 57-68 and 72-77 are cancelled; claim 76 is newly cancelled. Claims 56, 69, 70, 71 and 78 are under examination.

Rejections Withdrawn

All rejections made over claims 76 are hereby withdrawn in response to Applicants' cancellation of this claim.

Rejections Maintained/New Rejection

Claim Rejections - 35 USC § 103

Note that Applicants' Arguments will be addressed at the end of the two rejections under 35 U.S.C. 103, since they are directed at both.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 56 and 70-71 and 78 under 35 U.S.C. 103(a) as being unpatentable over Sampath et al. (U.S. Patent No: 6,498,142, filed 6 May 1996—of record) or, alternatively Sampath et al. (WO 97/41881--on Applicants' 1449 form filed 25 March 2010) and London et al. (Journal of hypertension. 1996; 14: 1139-46—of record) as set forth in previous Office actions (mailed 21 September 2006; 11 June 2007; 16 October 2008; 6 July 2009) is maintained for reasons of record and the following. The amended claims are drawn to a pharmaceutical composition comprising a

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therapeutically effective amount of an ACE inhibitor as recited in claim 56 and an OP/BMP morphogen as recited in claim 56, wherein said ACE inhibitor is at a concentration effective to synergistically stimulate the ability of said BMP morphogen to reduce proteinuria levels in a patient having diabetic nephropathy, wherein the morphogen is the polypeptide of SEQ ID NO: 3 (claim 70), or wherein the morphogen is a first polypeptide including at least a C-terminal cysteine domain of a protein selected from: a pro form, a mature form, or a soluble form of a second polypeptide, wherein said second polypeptide is: OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMP5, BMP6, or BMP9 (claim 71), in association with instructions for administering the composition to a mammal for treatment or prevention of chronic renal failure (claim 78—note that written instructions are not statutory subject matter in a patent, thus are given no patentable weight).

The first factor that must be considered when deciding whether claims are obvious, is to determine the scope and contents of the prior art. Sampath et al. teach methods and pharmaceutical preparations for use in the treatment of mammalian subjects at risk of chronic renal failure comprising administration of OP-1 formulated with appropriate excipients, as well as other BMPs and/or OPs. (See pages 21-25 of WO 97/41881). In Sampath et al., see the claims; column 24, lines 30-67 and SEQ ID NO: 16 which has 100% sequence similarity with SEQ ID NO: 3 of the instant application and encompasses the C-terminal seven cysteine domain recited in claim 71 (see also SEQ ID NO: 16 of WO 97/41881). Sampath et al. also teach that mechanical stresses on glomerulus due to hypertension worsens the early stage of chronic renal

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failure (column 2, lines 41-46; see p. 3; lines 12-13 of WO 97/41881). Sampath et al. further teach the exact same BMP morphogens at columns 11 lines 62-67 through 12, lines 1-17 as those recited in amended claim 56 (See pages 21-25 of WO 97/41881). Sampath et al. discuss at columns 21-24 that subjects indicated for treatment are those at risk of renal failure, and teaches measuring glomerular filtration rate or GFR as a method of estimating renal function. Finally, Sampath et al. teach at column 29, lines 3-36 that GFR showed OP-1 treated animals stabilized compared to controls and treated animals fared significantly better than controls by week 5 and that histological evaluation of renal tissue confirmed that OP-1 treatment preserved or maintained glomeruli, proximal and distal tubule structures and showed reduced degeneration (see p. 39 of WO 97/41881). In summary, Sampath et al. provide evidence of successful attenuation of renal failure in an art-accepted model for renal failure.

The second factor that must be considered is to ascertain the difference between the prior art and the claims at issue. Sampath et al. do not teach a pharmaceutical composition that also comprises an ACE inhibitor, nor do they teach the ACE inhibitor is at a concentration effective to synergistically stimulate the ability of said BMP morphogen to reduce proteinuria levels in a patient having diabetic nephropathy. London et al. teach the administration of ACE inhibitors (such as quinapril) at a single dose of 20mg for the treatment of hypertensive individuals with end-stage renal disease (see p. 1140, left column, 3rd paragraph through right column, 1st full paragraph) with the effect that ACE inhibition resulted in more efficient ventricular-vascular coupling and decreased left ventricular load. A packaged pharmaceutical is encompassed by the

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claims because each of the teachings suggest the administration of measured amounts of the compositions, thus encompass “packaged”. In summary, London et al. teach that ACE inhibition improves blood pressure in patients with renal disease, a condition which is often complicated with hypertension (see abstract of London et al., further see Sampath et al., column 2, lines 41-46).

The new limitation in claim 56 recites that the ACE inhibitor is at a concentration effective to synergistically stimulate the ability of said BMP morphogen to reduce proteinuria levels in a patient with diabetic nephropathy. In the instant case, since the claim does not recite a specific dose of ACE inhibitor, one must use the specification as a guide to such a dose. Paragraph 542 of the specification publication states that

[S]ingle, daily, biweekly, or weekly dosages of ACEI can be administered orally at an amount of about 0.01-300 mg/kg body weight, preferably 0.1-30 mg/kg BW, 0.1-3 mg/kg BW, 1-30 mg/kg BW, most preferably about 1-3 mg/kg BW, in, for example, drinking water, are appropriate for ACE inhibitors. The concentrations can be accordingly adjusted or alternatively expressed as the amount of drug that needs to be administered per day per kg of body weight, if other factors (such as the average body weight of a subject mammalian patient being treated, and the average amount of water consumed per day by said specific mammalian patient) are provided.

Thus the dose range for ACEIs in the specification is very broad. The specific dose of ACEI (enalapril) used in experiments taught at paragraph 612 of the specification publication is 100 mg/L in drinking water or approximately 8-16 mg/kg body weight (also pages 142-143). Rats in Example 4 (p. 142-143 of specification) weighed 200 - 250 g, which is equal to 0.2-0.25 kg, so this works out to a dose range of 1.6-4 mg enalapril, which happens to be within the range of the standard doses for adult humans. In short, the specification provides for a “concentration effective to synergistically stimulate the

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ability of said BMP morphogen to reduce proteinuria levels” that is within the standard dose range for ACEIs. Similarly, 20 mg represents a standard dose of quinapril for adult humans. This segues into a discussion of the third and fourth factors that must be considered. The third factor is to resolve the level of ordinary skill in the art. Given the teachings of London et al., it is clear that the person of ordinary skill in the art was aware of the standard doses for ACEIs. The fourth factor to consider is objective evidence present in the application for obviousness or non-obviousness. Since, as noted above, the POSITA would be aware of the standard doses for the different available ACEIs, there is no evidence of non-obviousness regarding the dose of ACEI.

The person of ordinary skill in the art would have been motivated to co-administer BMPs and ACEIs for several reasons. The POSITA would recognize that renal disease is known to be complicated with hypertension, as this is taught both in Sampath et al. and London et al. The POSITA would be motivated to administer a combination of BMP morphogens and ACE inhibitors to patients with renal disease because Sampath et al. teach BMP morphogens attenuate renal failure and London et al. teach that ACE inhibition improves blood pressure in patients with renal disease, thus the claims would have been obvious because the POSITA has good reason to pursue known options within his or her technical grasp. If this leads to anticipated success, it is likely to be the product not of innovation but of ordinary skill and common sense. Although neither Sampath et al. nor London et al. teach or suggest that this combination would lower proteinuria, the claims are drawn to a product and the ability of this product (BMP morphogen + ACE inhibitor) to lower protein in the urine is intrinsic to

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the functioning of this combination. As stated above, the discussed prior art disclose that both BMP morphogens and ACE inhibitors are indicated for the treatment of renal disease, and the POSITA would be motivated to administer them in combination.

Furthermore, the person of ordinary skill in the art could have reasonably expected success because the prior art recognized the success of both in treating renal failure.

Thus the claims do not contribute anything non-obvious over the prior art.

The rejection of claim 69 under 35 U.S.C. 103(a) as being unpatentable over Sampath et al. (U.S. Patent No: 6,498,142) and London et al. (Journal of hypertension. 1996; 14: 1139-46) as applied to claims 56 and 70-76 and 78 in the immediately preceding paragraph and Salvetti (Drugs. 1990; 40: 800-28—of record) as set forth in previous Office actions (mailed 21 September 2006; 11 June 2007; 16 October 2008; 6 July 2009) is maintained for reasons of record and the following. Claim 69 limits the ACE inhibitor to enalapril.

The discussion above regarding how Sampath et al. and London et al. meet the limitations of claims 56, 70, 71 and 78 is applicable here and hereby incorporated. The prior art differs from the claims in that neither Sampath et al. nor London et al. teach that the ACE inhibitor is enalapril. Salvetti et al. review and compare the ACE inhibitors, including enalapril, thus this article suggests the similarity of action between ACE inhibitors on the market. Note especially, p. 802, whole page, which contains a discussion on the biochemistry and pharmacokinetics of ACE inhibitors. Note also, p. 802, right column, 3rd paragraph, where it is said that enalapril is more potent and has a longer duration of action. Given the teachings of Sampath et al. and London et al.,

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which suggest that BMP morphogens and ACE inhibitors, respectively, are useful for treating renal disease, it would have been obvious to the POSITA at the time the invention was made to modify the teachings of Sampath et al. and London et al. by formulating a pharmaceutical containing the ACE inhibitor, enalapril, as taught in Salvetti, because Salvetti states that enalapril is more potent and has a longer duration of action (p. 802, right column, 3rd paragraph) and additionally, Salvetti suggests the similarity of the many commercially available ACE inhibitors, thus the knowledge of their pharmacokinetics and efficacy for reducing hypertension with many species of ACE inhibitors were well known in the art at the time of filing. The person of ordinary skill in the art would have been motivated to make the change because renal disease is almost always complicated by hypertension and the greater potency and duration of enalapril would make it an obvious choice for substitution of one ACE inhibitor for another. Finally, the person of ordinary skill in the art could have reasonably expected success because the prior art recognized the success of both BMP morphogens and enalapril in treating patients with renal failure. Thus the claims do not contribute anything non-obvious over the prior art.

Response to Arguments

1) Applicants argue at pages 7-8 that nowhere in any of Sampath, London, Ritz and de Zeeuw is there any teaching or suggestion to combine a BMP and an ACE inhibitor, let alone, to combine an ACE inhibitor selected from the Markush group of inhibitors wherein the ACE inhibitor is at a concentration effective to synergistically stimulate the ability of the BMP morphogen to reduce proteinuria. Thus, only those recited ACE inhibitors that are present at those concentrations that are effective to synergistically stimulate the ability of the BMP morphogens to reduce proteinuria levels are claimed. This feature is also nowhere taught or suggested in any of the references.

This argument has been fully considered but is not found persuasive. First, quinapril is one of the ACEIs that is recited in claim 56. Second, the specification is very broad with respect to suitable dosages of ACEIs at paragraph 542 of the specification publication:

As a general matter, single, daily, biweekly, or weekly dosages of ACEI can be administered orally at an amount of about 0.01-300 mg/kg body weight, preferably 0.1-30 mg/kg BW, 0.1-3 mg/kg BW, 1-30 mg/kg BW, most preferably about 1-3 mg/kg BW, in, for example, drinking water, are appropriate for ACE inhibitors. The concentrations can be accordingly adjusted or alternatively expressed as the amount of drug that needs to be administered per day per kg of body weight, if other factors (such as the average body weight of a subject mammalian patient being treated, and the average amount of water consumed per day by said specific mammalian patient) are provided. The present effective dose can be administered in a single dose or in a plurality (two or more) of installment doses, as desired or considered appropriate under the specific circumstances.

Note also the sentence, “the concentrations can be accordingly adjusted or alternatively expressed as the amount of drug that needs to be administered per day per kg of body weight...,” thus suggesting that one of ordinary skill in the art would know how to do this. The specific dose of ACEI (enalapril) used in experiments taught at paragraph 612 of the specification publication is 100 mg/L in drinking water or approximately 8-16 mg/kg body weight (also pages 142-143). Rats in Example 4 (p. 142-143 of specification) weighed 200 - 250 g, which is equal to 0.2-0.25 kg, so this approximates a dose range of 1.6-4 mg enalapril.

Third, the dose range of 1.6-4 mg enalapril happens to be within the range of the standard doses of enalapril for adult humans. Evidence for this is provided in the form of the website on enalapril dosing at medicinenet.com/enalapril/article.html (downloaded

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2 May 2010), which shows the preparations of enalapril are 2.5, 5, 10 and 20 mg in oral form and 1.25 mg/ml for injection. A dose range of 1.6-4mg as taught in the example correlates to the low dose oral form or the preparation for injection. The art of record also teaches oral doses between 10-40 mg (for instance, see Reams et al. J. Clin Hyperens, 1996; 1: 55-63—on Applicants' 1449 form). Quinapril is a related but distinct drug, however, the 20 mg dose taught in London et al. represents a standard dose of quinapril for adult humans. Evidence for this is provided by the website on quinapril dosing at rxlist.com/accupril-drug.htm (downloaded 6 May 2010), which shows the preparations of quinapril as including 5, 10, 20 and 40 mg tablets (i.e., standard preparations of the oral form of quinapril contains twice as many mg as that for standard preparations of enalapril). Salvetti et al. (of record) teach that the pharmacokinetics of various ACEI, including enalapril and quinapril were well known in the art (see whole document); they also teach that enalapril is more potent and has a longer duration of action, which would explain the lower dose preparations compared to quinapril. In short, these references show the standard formulations of two well known ACEIs and the specification only provides for a "concentration effective to synergistically stimulate the ability of said BMP morphogen to reduce proteinuria levels" that is ***within the standard dose range*** for ACEIs, thus there is no evidence of a surprising or unexpected dose or concentration of a given ACEI that would result in synergism with BMPs. In summary, the specification teaches that standard doses of ACEIs would result in synergism.

2) Applicants argue at p. 8, 2nd paragraph that In re Soni supports the rebuttal of the prima facie case of obviousness in the instant application because In re Soni

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indicates that a showing of unexpected results is "to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *Id.* at 1687. The synergy that results from the claimed combination of a BMP and the specifically recited ACE inhibitors is clearly a superior property or advantage. Moreover, applicants have demonstrated that the synergistic property of the reduced proteinuria levels was surprising or unexpected. See, Example 4, specification pages 142-143.

This argument has been fully considered but is not found persuasive. First, as noted in the Advisory action mailed 29 September 2009, the fact patterns differ between the instant case and those set forth in *In re Soni*. The *Soni* claims are product by process claims that result in a physical/structural difference that imparts greater tensile strength etc., whereas the instant claims are drawn to compositions and dosages already known in the art. Second, as noted in the explanation to Argument 1 above, the amendment to the claims does not render the claims unobvious over the prior art because the specification teaches only that standard doses of ACEIs would result in synergism with BMPs, and there is nothing unexpected or surprising about using a standard dose range. Third, the MPEP provides specific guidance about this issue, namely, while a new and unobvious **use** (i.e., a process) of old structures may be patentable (see MPEP 2112.02) an **old product does not become patentable upon the discovery of a new property**. As noted above, the concentration of ACEI taught in the specification does not differ from the standard dose range. See MPEP 2112: I.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >*In re Crish*, 393 F.3d 1253, 1258,

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73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.” *Id.*< See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103.

In short, Applicants’ discovery of synergism between BMPs and ACEIs in the treatment of proteinuria does not render the composition comprising a BMP and an ACEI (which is administered in a standard dose preparation) unobvious over the prior art, since the prior art taught 1) the treatment of BMPs and ACEIs for treatment of renal disease patients and 2) the standard dose preparations of ACEIs are not unobvious since they were known in the art.

3) At p. 9, proteinuria levels. Salvetti does not remedy this deficiency. Salvetti only discloses that enalapril is more potent and has longer duration of action than other ACE inhibitors. That disclosure in no way would motivate the skilled worker to combine enalapril with BMPs to synergistically reduce proteinuria levels. Therefore, the combination of Sampath, London and Salvetti does not render claim 69 obvious for the same reasons that the combination of Sampath and London does not render the claim obvious. Accordingly, applicants respectfully request that the Examiner withdraw this rejection.

This argument has been fully considered but is not found persuasive. The Examiner’s response to Arguments 1 and 2 are hereby incorporated.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Klahr (Semin Nephrol. 2001; 21: 133-45 teaches that "OP-1 was more effective than ACE inhibitors (enalapril) in preventing tubulointerstitial fibrosis and preserving renal function." See p. 142, right column.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

/Bridget E Bunner/
Primary Examiner, Art Unit 1647